



UNITED STATES PATENT AND TRADEMARK OFFICE

27

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,110	04/05/2001	Elizabeth A. Wang	CIBT-P03-031	7778

28120 7590 06/27/2006

FISH & NEAVE IP GROUP
ROPES & GRAY LLP
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER

TELLER, ROY R

ART UNIT	PAPER NUMBER
----------	--------------

1654

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/827,110

Applicant(s)

WANG, ELIZABETH A.

Examiner

Roy Teller

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 63,65-68 and 70-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63,65-68,70-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1654

DETAILED ACTION

This office action is in response to the amendment, received 4/7/06, in which applicant amended claim 63.

Claims 63, 65-68, and 70-75 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 63, 65-68, and 70-75 are/stand rejected under 35 U.S.C. 103(a) as being unpatentable by Ingham (USPN 5,844,079) in view of Tabin (USPN 6,884,775) for reasons of record which are restated below.

The claimed invention is drawn to a preparation comprising a sonic hedgehog polypeptide sequence in which the polypeptide is formulated for topical application, and which polypeptide is formulated on a sponge, bandage, dressing, or film.

Ingham et al. teaches topical preparations comprising sonic hedgehog polypeptides encoded by hedgehog related genes, see e.g., for example, column 3. Ingham teaches the Shh polypeptide can comprise a fragment of at least 50, 100 or 150 amino acids in length within the N-terminal

Art Unit: 1654

half thereof, see, e.g., for example, column 3. In addition, Ingham discloses hedgehog polypeptides which include Shh sequences corresponding approximately to the natural proteolytic fragments of the hedgehog proteins, such as from about Cys-24 through Glu-188, or from about Asn-189 through Ala-475 of the human Shh protein, or analogous fragments thereto, see, e.g., for example, column 3. Ingham discloses methods of introduction of exogenous hedgehog polypeptides at the site of treatment include hydrogels that can be used to form an implant such as within a gauze for sustained release at a particular target site, see e.g., for example, column 52, lines 42-64. Ingham does not teach the use of bandages or dressings.

Tabin et al. teaches hedgehog polypeptides, which encompass preparations of hedgehog proteins and peptidyl fragments, can be used to make plasters, bandages, dressings, gauze pads and the like, see, i.e., for example, columns 53-54, and column 57, lines 8-14.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Ingham with the beneficial teachings of Tobin, because Tobin discloses preparations of hedgehog polypeptides can be used to make plasters, bandages, dressings, gauze pads and the like.

Applicant's arguments were carefully considered but were not found persuasive.

Applicant contends that the prior art cited teaches away from using hydrogels as part of a topical preparation. Applicant further contends that the prior cited art neither teach nor suggest the use of hedgehog polypeptides in, for example, the promotion of hair growth. However, the examiner contends that the prior art cited describes methods of introduction of exogenous hedgehog at the site of treatment include topical treatment, which include hydrogels that can be

Art Unit: 1654

used within a gauze for sustained release at a particular target site, see, i.e., for example, patent '079, column 52, line 45, and patent '775, column 53, line 30, column 54, lines 4-6, and column 57, lines 13-14. The use of hedgehog polypeptides in, for example, the promotion of hair growth is an intended use limitation which the hedgehog polypeptides would inherently possess.

Conclusion

All claims are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

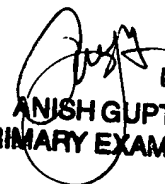
Art Unit: 1654

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RT
1654
6/16/06

RT

 6/23/06
ANISH GUPTA
PRIMARY EXAMINER